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SUBJ: Two CLSI Citizen's Petition: 1) June 21, 2006 Petition (Docket No. 2006P-0271); and 2) August 23, 2006 Petition (Docket No. 2006P-0348).

To whom it may concern:

The Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) are writing in support of the Clinical and Laboratory Standards Institute's (CLSI) Citizen's Petition dated June 21, 2006 (Docket No. 2006P-0271) and its August 23, 2006 Petition (Docket No. 2006P-0348). We support the premise of CLSI's June 21, 2006 Petition that the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) approve susceptibility test devices especially those with software that provide interpretive susceptibility criteria based on either FDA's or CLSI's thorough review and critique of available data. CLSI's position is consistent with CDRH's previous practice of immediately adopting CLSI antimicrobial agent interpretive criteria for purposes of assessing the performance of medical devices used by clinical microbiology laboratories to interpret the results of susceptibility tests. CLSI has published such data since 1972. FDA has a long history of accepting such data without delay or incident.

Because of the rapid evolution of resistance of bacterial pathogens to antimicrobials, we are concerned that FDA's recent adoption of new procedures (i.e., applying FDA's existing Citizen Petition process to CLSI breakpoints submission and adoption) may have inadvertent, but detrimental, consequences for patient care. In particular, we are concerned that the new process will delay the adoption of alternative revised breakpoints when new mechanisms of antimicrobial resistance are recognized, which could lead to medical errors and jeopardize patient safety. For this reason, we support a return to FDA's past practice of immediately adopting CLSI standards. If this is not feasible, then IDSA urges the agency to dedicate sufficient resources and staff to CDRH's and the Center for Drug Evaluation and Research's review of future CLSI Citizen's Petitions so that CLSI recommendations may move expeditiously through review. We also ask that the agency provide timely FDA Medical Officer participation and input into discussions and decisions made at each CLSI meeting, as originally designed in the CLSI consensus process. We also ask for a rapid, fast track response by FDA to CLSI requests to be completed within 180 days. As the FDA Medical Officer will be a full participant in the consensus process at each CLSI meeting, the Agency will actually have an additional 6 months to review, consider, and request information prior to submission of the CLSI request. If such reviews routinely exceed 180 days, more frequent meetings of CLSI Working Groups, FDA, and teleconferences of the CLSI Antimicrobial Susceptibility Testing Subcommittee should be held between routinely scheduled twice yearly CLSI meetings.

IDSA also supports CLSI's position in its June 21 Petition (Docket No. 2006P-0271) that CDRH clear fluconazole disks for performance of rapid, cost-effective antifungal susceptibility testing of yeasts by clinical laboratories as well as CLSI's August 23, 2006 Petition (Docket No. 2006P-0348) requesting CDER to revise the approved drug label for vancomycin to include the new vancomycin interpretive criteria of 2 µg/mL or less, susceptible; 4 to 8 µg/mL, intermediate; and 16 µg/mL or greater, resistant for *S. aureus*.

Thank you for the opportunity to comment. Should you have any questions please feel free to contact Robert J. Guidos, JD at 703-299-0202 or rguidos@idsociety.org.

Sincerely,

Martin J. Blaser, MD